SECTION 2 – 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

K013946

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 8807.92

FEB 2 7 2002

Contact Person
Nancy Norris
Program Manager
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Device Name
Trade Name: FLEX 10 Accessory for the AFx Microwave Ablation System
Common Name: None
Classification Name: Cryosurgical unit and accessories (21 CFR 878.4350);

Predicate Devices

AFx Microwave Ablation System and Accessories	K003978
CryoGen Cardiac Cryosurgery System	K974320
Heartport Maze System: Cryoprobe Set	K970496

Device Description
The FLEX 10 Accessory is a surgical ablation probe that directs the microwave energy developed by the AFx Microwave Generator into the target tissue. The FLEX 10 Accessory is a sterile, hand-held, single-use, surgical ablation device. The ablative microwave energy emanates from an antenna contained in the ablation sheath at the distal end of the device.

The FLEX 10 Accessory has a flexible 2 m long insulated coax cable that attaches the Probe to the Microwave Generator output cable. The flexible cable is attached to a 24 cm long hand grip, followed by a 15 cm section of stainless steel hypotube, followed by a highly flexible PTFE ablation sheath, which contains the movable microwave energy delivery antenna. The end of the ablation sheath is attached to a PEBAX positioning sheath and sutures to aid in the proper placement of the ablating sheath. Moving the sliding ring on the hand grip moves the antenna to discrete numbered locations in the ablating sheath. The position of the antenna within the ablating sheath is displayed to the user by the position indicator of the sliding ring on the hand grip.

Indications for Use
The FLEX 10 Accessory is intended to be used with the AFx Microwave Ablation System for the surgical ablation of soft tissue, in addition to striated, cardiac and smooth muscles. The system is designed to ablate tissue by the induction of thermal necrosis in the targeted tissues.

510(k) Summary – continued

Testing in Support of Substantial Equivalence Determination

The results of bench testing and biocompatibility testing support the substantial equivalence claims of the FLEX 10 Accessory for the AFx Microwave Ablation System in the above indication. The animal testing demonstrated the reliability of the sliding antenna concept.

Substantial Equivalence Conclusion

Substantial equivalence is based on the fact that the FLEX 10 Accessory for the AFx Microwave Ablation System has equivalent data-based intended uses as the predicate AFx Microwave Ablation System with its LYNX and FLEX Ablation Probe Accessories. There are no significant technological differences between the FLEX 10 and cleared microwave ablation probes. There are no new questions of safety or efficacy raised by the AFx Microwave Ablation System with any of its ablation probes vis-à-vis the predicate cryogenic ablation devices. Therefore, it can be concluded that the FLEX 10 Ablation Probe Accessory for the AFx Microwave Ablation System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 7 2002

Ms. Nancy Norris
Program Director
Afx, Inc.
47929 Fremont Boulevard
Fremont, CA 94538

Re: K013946
Trade/Device Name: FLEX 10 Accessory for the Afx Microwave Ablation System
Regulation Number: 878.4350
Regulation Name: Cryosurgical unit and accessories
Regulatory Class: II
Product Code: NEY
Dated: November 28, 2001
Received: November 29, 2001

Dear Ms. Norris:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K013946

Device Name: FLEX 10 Ablation Probe Accessory for the AFx Microwave Ablation System

Indications for Use

The FLEX 10 Accessory is intended to be used with the AFx Microwave Ablation System for the surgical ablation of soft tissue, in addition to striated, cardiac and smooth muscles. The system is designed to ablate tissue by the induction of thermal necrosis in the targeted tissues.

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013946

(Division Sign-Off)
Division of General, [illegible]
and Neurological [illegible]

510(k)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)